

C14a11 (c) exposing the syrup to a pressure and temperature that causes [boiling] foaming of the syrup, thereby forming an FGM.

93. (amended) An FGM incorporating a [substance] biologically active agent to be preserved, formed according to the method of claim 91.

94. (amended) A method for producing thin, foamed glass matrices (FGMs),
SUB D16 comprising the steps of:

C15 (a) preparing an initial mixture comprising at least one glass matrix-forming carbohydrate, carbohydrate alcohol or carbohydrate derivative, an aqueous solvent therefor, and a foam-promoting additive which is a volatile organic solvent;

(b) evaporating a proportion of the aqueous and organic solvents from the mixture to obtain a syrup; and

(c) exposing the syrup to a pressure and temperature that causes [boiling] foaming of the syrup, thereby forming an FGM.

C16 96. (amended) An FGM incorporating a [substance] biologically active agent to be preserved, formed according to the method of claim 94.

Remarks

Passage of the claims, as amended, to allowance as agreed in the interview recorded below is respectfully requested.

Record is made of an interview with Examiners Chin and Nguyen which took place on October 14, 1997 and was attended by Dr. Camilo Colaco (Director of Intellectual Property for the Assignee), and applicant's representatives Drs. Johnston and Lehnhardt. Applicant and applicant's representatives thank Examiners Chin and Nguyen for courtesies extended during the interview and for their helpfulness. During the interview, newly amended claims, 35 USC § 112 issues and the prior art were discussed. Agreement was reached that the claims, as amended, would more clearly differentiate over the prior art describing methods of making cotton candy. It was also agreed that several of the amendments previously presented would be removed as they

had not been persuasive and were unnecessarily limiting. It was agreed that the pending claims are those as amended November 20, 1996. These claims are attached hereto as Exhibit A.

The claimed invention is directed to novel methods for producing novel formulations of foamed glass matrices (FGMs). The methods involve producing a carbohydrate syrup and "boiling" the syrup under reduced pressure to form bubbles and evaporate the solvent. This rapid boiling/evaporation causes the carbohydrates to solidify into very thin sheets of amorphous glass. This is clearly demonstrated in the accompanying photographs and samples. The large surface area of the FGMs results in rapid and complete solubility of the FGMs and any substances therein and other advantages described in the specification.

Claim Rejections Under 35 USC § 112 ¶1

Claims 49, 54-59, 61-69, 72, 73, 75, 81-90, 93 and 96 are rejected under 35 USC § 112, first paragraph. At the interview, and during prior telephone interviews, Examiner Chin agreed that the scope of these claims is patentable under Section 112, first paragraph as enabling for all stabilizing polyols. Applicant appreciates withdrawal of this rejection.

A further rejection was made under 35 U.S.C. § 112, first paragraph, on the grounds that the specification does not teach modifying the carbohydrate chemically or enzymatically. This presumably refers to claim 5. This rejection was not discussed at the interview nor was it addressed in the Advisory Action. Should the rejection stand, the arguments presented in the previous response should be compelling. To wit, in order to sustain such a rejection, the Examiner must show that one of skill in the art could not make such modifications. Not every experimental detail need be provided in a specification as one of skill in the art is presumed to know standard procedures. It is well within the skill of the art to modify carbohydrates using readily available materials and according to knowledge in the art. Also, many of these modified carbohydrates are commercially available. The artisan will readily appreciate that the list of exemplary carbohydrates on page 8 of the specification includes those obtained "by reduction"

and by other chemical and enzymatic procedures, and that procedures not indicated or implied in the disclosure are nonetheless incorporated in the scope of the invention.

In fact, the skilled artisan has available a wide variety of publications with information as to types of modifications and methods of making such modifications. Accompanying the previous amendment was a Supplemental Information Disclosure Statement disclosing a number of representative, but not exhaustive, publications related to carbohydrate modifications. Several articles are general. For instance, *Organic Chemistry*, by Streitwieser, Jr. and Heathcock eds. is a standard chemistry textbook published in 1976. An entire chapter is provided and discusses sugars in general and a wide variety of modifications. The *Angewandte Chemie* article entitled "Advances in Selective Chemical Syntheses of Complex Oligosaccharides", published in 1982, discusses chemical syntheses of complex carbohydrates and provides a number of modifications. The article entitled "New Methods for the Synthesis of Glycosides and Oligosaccharides - Are There Alternatives to the Koenigs-Knorr method?", published in 1986 provides a number of possible modifications and methods of making the modifications. More specific carbohydrate modifications are discussed in the following: Prey, US Patent No. 3,956,278 "Novel Mixed Partial Esters of Carbohydrates" (1976); Goren and Jiang, "(α -D-Glucopyranosyluronic acid) (α -D-Glucopyranosiduronic acid) and Simple Derivatives" (1980); Takahiko et al., EP Patent Application No. 0,714,905, "Process for Producing Trehalose Derivatives" (1996); Junji et al. EP Patent Application No. 0,356,154 "Trehalose Derivatives" (1990); and Nishikawa et al. US Patent No 4,684,719 " α,α -Trehalose Fatty Acid Diester Derivative" (1987).

Thus, it is clear that a wide variety of modifications and methods of making such modifications are available to one of skill in the art wishing to make and use the claimed invention. There is no evidence that one of skill in the art could not use these or other publications known in the art at the time of filing to make and use the invention as claimed. Consequently, the claims are enabled under 35 USC § 112, first paragraph.

The Examiner states on page 4, lines 3-12 that the specification does not teach how carbohydrates can be chemically or enzymatically modified, and that the list of carbohydrates on

page 8 is a list of compounds which are already modified. Claim 5 as amended is directed to the embodiment of claim 3 wherein the carbohydrate is a “chemically or enzymatically modified carbohydrate.” Applicants are claiming a method of making a glass forming matrix material optionally using modified carbohydrates, they are not claiming methods of modifying carbohydrates. As described in detail in the specification, such modified carbohydrates can be obtained commercially, or made using methods which are well developed in the art. Applicants need not teach what is known in the art. Thus, based on the teachings of the specification and the general knowledge in the art at the time of filing, one of ordinary skill could readily practice the claimed methods using different modified carbohydrates.

Examiner Chin objected to the term “substance” or “biological substance” in claims 49, 62, 65, 70, 72, 73, 75, 96 and claims dependent thereon. It was agreed at the interview that the terms would be replaced with “biologically active agent” which is inherently supported in the specification. This amendment has been effected in the relevant claims.

Claim Rejections Under 35 USC § 102(b)

Claims 1-4, 6, 8, 9, 13-18, 24, 30-34, 36, 40, 41, 49, 54, 55, 62, 63, 71, 72, 78, 83-85, 90-91 and 93 were rejected under 35 USC § 102(b) as anticipated by Chivers (US Patent No. 3,557,717). As discussed during the interview, the claimed method is completely different than the Chivers method used to make cotton candy. Moreover, the product obtained is a thin-walled amorphous glass matrix which is completely different than the filamentous, crystalline cotton candy produced by the Chivers method. This difference was agreed at the interview to be more clearly stated by changing “boiling” to “foaming.” This amendment has been effected in the relevant claims.

The claims, as amended, were agreed at the interview to more clearly distinguish the claimed invention over Chivers. Applicant appreciates the withdrawal of this rejection.

Rejection Under 35 USC § 103

Claims 10, 12, 19-23, 25-29, 42, 44-47, 57, 59, 61, 64-67, 69, 70, 73, 75, 81, 86-87, 94 and 96 were rejected under 35 USC § 103 over Chivers in view of Black, Samuels et al. and Wettlaufer.

Inasmuch as the claims are considered to more clearly distinguish over Chivers, the combination of Chivers and the cited references would not render the claimed invention unpatentable.

In the unlikely event that the transmittal letter is separated from this document and the Patent Office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Assistant Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952**. However, the Assistant Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

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Respectfully submitted,

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